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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
MATTER, KRISTEN CLARETTE

ART UNIT	PAPER NUMBER
3771	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,860	DOUGLAS ET AL.	
	Examiner	Art Unit	
	KRISTEN C. MATTER	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the amendment filed 5/14/2010. Claims 1-18 were cancelled and claims 19-79 were added. Thus, claims 19-79 are currently pending in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Froehlich et al. (US 5,551,419, herein referred to as "Froehlich") in view of Berthon-Jones (US 5,704,345) and Hill (US 2002/0088465).

Regarding claims 19-21, 23, 34-38, 43, 50-52, 54, 65-69, and 74, Froehlich discloses CPAP apparatus having a blower (12), a patient interface (11), an air delivery conduit (14), a pressure sensor (16), a flow sensor (15), an air synchrony module to determine transitions between inhalation and exhalation (see column 2, lines 60-65 and column 6, lines 15-20 for example), and a control mechanism (17) programmed to provide positive pressure in accordance with a predetermined pressure-time template (see Figure 4). Froehlich further discloses that the apparatus controls blower operation by automatically determining the presence of sleep disordered breathing and automatically determining a treatment pressure in accordance with the presence of sleep disordered breathing (column 5, lines 35-55), setting at least one characterizing

parameter of the pressure-time template to the treatment pressure (column 6, lines 15-27 and column 13, lines 20-30), and controlling the blower to delivery a supply air in accordance with the template and in synchrony with the patient's breathing cycles (via lines 19 and 20).

Froehlich discloses determining sleep disordered breathing, such as apnea, from "known techniques" but does not specifically mention an index. However, indices are well known and commonly used in the art for determining the presence of a sleep disordered breathing event. In addition, Berthon-Jones discloses a similar CPAP apparatus that determines the presence of apneas by calculating several indices, including both an index for indicating apnea and an index indicative of flow flattening (see abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used several indices for determining the presence of sleep disordered breathing in the system of Froehlich because it would have allowed a user to use a well known means for determining the presence and/or severity of sleep disordered breathing and to provide therapy as needed. Such a modification would involve the mere substitution of a well known method of determining apnea episodes in a well known device to yield predictable results that do not patentably distinguish an invention over the prior art.

Froehlich as modified by Berthon-Jones further lacks setting one pressure parameter to a first treatment pressure in accordance with the first index during expiration and another pressure parameter to a second treatment parameter based on the second index during inspiration. However, Hill discloses a similar CPAP apparatus that uses several indices to vary both the IPAP and EPAP to counter a sleep disordered breathing event (see paragraphs 11, 12, 49, and 53 for example). Therefore, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to have further modified Froehlich to adjust both the EPAP and IPAP as taught by Hill depending on the severity of the sleep disordered breathing event and/or to treat the patient more comfortably by adjusting both the minimum and maximum pressures only as necessary. Furthermore, there is nothing structurally in Froehlich that would prevent the controller from adjusting both the EPAP and IPAP based on the indices and it appears as though Froehlich would perform equally well with both the EPAP and IPAP being adjusted.

Regarding claims 22, 44, 53, and 75, Froehlich discloses the template can be a square wave (see column 2, line 64).

Regarding claims 24-26, 28, 39, 55-57, 59, and 70, the modified Froehlich reference discloses controlling IPAP and EPAP levels and incrementally increasing or decreasing those values in accordance with the detection of apneas (which would be considered maximum and minimum values, the IPAP being greater than the EPAP).

Regarding claims 27, 29, 41, 42, 58, 60, 72, and 73, Froehlich discloses CPAP pressure is generally delivered between 3-20 cm H20, which overlaps the claimed pressures.

Regarding claims 30, 40, 61, and 71, Froehlich does not specifically disclose a maximum swing/pressure difference. However, absent a critical teaching and/or showing of unexpected results from having a maximum swing, examiner contends that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a maximum swing in order to prevent the swing from getting too large if a high number of sleep disorder breathing events was detected, to increase comfort to the patient by keeping the maximum and minimum pressure levels closer to one another, and to allow the device to effectively get to the desired min/max pressure levels (i.e., if the swing is too large the system might not be able to

reach the desired pressures in the given amount of time of the breathing cycle). In addition, since the pressures are generally between 3-20 cmH20 in CPAP systems, it would have been obvious to ensure that the pressures stayed within this range, and thus are subject to a maximum swing. Furthermore, there is nothing structurally that would prevent the use of a maximum swing and it appears as though the device would work equally well with a maximum swing when increasing/decreasing the pressure.

Regarding claims 31, 32, 47-49, 62, 63, 78, and 79, Froehlich, Berthon-Jones, and Hill all disclose decreasing pressures in the absence of sleep disordered breathing events (see column 1, lines 55-60 of Froehlich and paragraphs 13, 51, 69, 72, and 75 of Hill for example). It thus would have been obvious to adjust the first and second treatment pressures in accordance with the absence of events determined by their respective indices.

Regarding claims 33, 46, 64, and 77, Froehlich does not specifically mention a look-up table. However, the controller is programmable and look-up tables and arrays are well known and commonly use processing techniques for creating signals. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have had the breathing signal be derived from a look-up table or array because it would have provided a well known means of creating a safe breathing profile for a user. Such a modification would appear to involve the mere substitution of a well known method in a well known device to yield predictable results that do not patentably distinguish an invention over the prior art.

Regarding claims 45 and 76, Froehlich lacks the template being a shark-fin wave. However, shark-fin waves are well known and commonly used in CPAP systems as evidenced by Hill (see Figure 4 for example). Therefore, it would have been obvious to one of ordinary

skill in the art at the time the invention was made to have used a shark-fin wave in the template of the modified Froehlich device in order to more comfortably delivery gas to a patient by making pressure changes less abrupt for example. Furthermore, there is nothing structurally preventing the use of a shark-fin wave (or any other well known waveform for that matter) in Froehlich's system and it appears as though Froehlich would perform equally well with a shark-fin wave. Such a modification would involve the mere substitution of a well known method/waveform in a well known device to yield predictable results that do not patentably distinguish an invention over the prior art.

Response to Arguments

Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771